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- 792.120 Protocol.
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- 792.185 Reporting of study results.
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AUTHORITY: 15 U.S.C. 2603.

SOURCE: 54 FR 34043, Aug. 17, 1989, unless otherwise noted.

Subpart A—General Provisions

§ 792.1 Scope.

(a) This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing. This part is intended to ensure the quality and integrity of data submitted pursuant to testing consent agree-

ments and test rules issued under section 4 of the Toxic Substances Control Act (TSCA) (Pub. L. 94-469, 90 Stat. 2006, 15 U.S.C. 2603 *et seq.*).

- (b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after September 18, 1989.
- (c) It is EPA's policy that all data developed under section 5 of TSCA be in accordance with provisions of this part. If data are not developed in accordance with the provisions of this part, EPA will consider such data insufficient to evaluate the health and environmental effects of the chemical substances unless the submitter provides additional information demonstrating that the data are reliable and adequate.

§ 792.3 Definitions.

As used in this part the following terms shall have the meanings specified:

Batch means a specific quantity or lot of a test, control, or reference substance that has been characterized according to §792.105(a).

Carrier means any material, including but not limited to, feed, water, soil, and nutrient media, with which the test substance is combined for administration to a test system.

Control substance means any chemical substance or mixture, or any other material other than a test substance, feed, or water, that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance for chemical or biological measurements.

EPA means the U.S. Environmental Protection Agency.

Experimental start date means the first date the test substance is applied to the test system.

Experimental termination date means the last date on which data are collected directly from the study.

FDA means the U.S. Food and Drug Administration.

Person includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

Quality assurance unit means any person or organizational element, except